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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
GAMBEL,P	
ART UNIT	**PAPER NUMBER**
1644	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

DETAILED ACTION

1. Applicant's communication, filed 10/23/00 (Paper No. 6), has placed this application in compliance with the Sequence Rules.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-15, 28, 29 drawn to methods of vaccination with CD40L-enhanced cells, classified in Class 424, subclass 93.71.

II. Claims 16-26, 28, 29 drawn to methods of vaccination by administering an APC contacted with CD40L-enhanced cells ex vivo, classified in Class 424, subclass 93.71.

III. Claims 27-29, drawn to methods of vaccination with an opsonin-enhanced pathogenic cells and CD40L-enhanced pathogenic cells, classified in Class 424, subclass 93.71.

IV. Claims 30-37, drawn to a CD40L-enhanced pathogenic cell comprising lipids, classified in Class 435, subclass 325.

V Claims 38-59, drawn to a CD40L-enhanced cell comprising cytokines, classified in Class 435, subclass 325. Claims

VI. Claims 60-68, drawn to engineered ligands for CD40, classified in Class 530, subclass 350, 387.1.

3. (Inventions IV and I/II/III) as well as (Inventions V and III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the cells can be used for ex vivo bioassays, as immunogens, and as sources to obtain proteins of interest (e.g. CD40L).

4. Inventions I/II/III are different methods, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

Therefore they are novel and unobvious in view of each other and are patentably distinct.

5. Inventions IV/V/VI are different products. Cells comprising pathogenic cells and CD40L engineered cells; CD40L engineered cells and engineered CD40 ligands are distinct because their structures and modes of action are different. Therefore, they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-Vi is not required for any other group from Groups I-Vi and Groups I-VI have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed Groups I/II/III/IV/V/VI: wherein the CD40L enhanced cells or engineered CD40 ligand is/further comprises:

A) unmodified (e.g. does not comprise a lipid or a cytokine);
B) opsonin,
C) cytokine
D) lipid
E) and combinations thereof.

These species are distinct because their structures and physicochemical properties differ to the extent that a person of ordinary skill in the art would not envision one in view of the other. Therefore, they are separate and patentably distinct species

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, currently; claims 1, 15, 20, 27, 38 60 and 68 generic.

Depending on which Group is elected; applicant is required to elect a particular species of said Group, including a particular combination (e.g. CD40L enhanced cell, comprising an opsonin and a cytokine); if so desired.

8. In addition to Section 7 above; applicant is required a further species from the following, if appropriate:

A) CD40 Ligand:

This application contains claims directed to the following patentably distinct species of the claimed Groups I/II/III/IV/V/VI: wherein the CD40L enhanced cells or engineered CD40 ligand is/further comprises an CD40 ligand selected from the group consisting of:

A) CD40 or
B) CD40-specific antibody.

These species are distinct because their structures and physicochemical properties differ to the extent that a person of ordinary skill in the art would not envision one in view of the other. Therefore, they are separate and patentably distinct species

B) Opsonin:

This application contains claims directed to the following patentably distinct species of the claimed Groups I/II/III/IV/V/VI: wherein the CD40L enhanced cells or engineered CD40 ligand is/further comprises an opsonin selected from the group consisting of:

A) mannose binding protein or
B) alpha chain of C3b.

These species are distinct because their structures and physicochemical properties differ to the extent that a person of ordinary skill in the art would not envision one in view of the other. Therefore, they are separate and patentably distinct species

C) Cytokine:

This application contains claims directed to the following patentably distinct species of the claimed Groups I/II/III/IV/V/VI: wherein the CD40L enhanced cells or engineered CD40 ligand is/further comprises an cytokine selected from the group consisting of:

A) IL-2,
B) IL-4,
C) IL-6,
D) IL-10,
E) IL-12,
F) TNF-α,
G) IFN-γ,
H) chemokine, or
I) GM-CSF.

These species are distinct because their structures and physicochemical properties differ to the extent that a person of ordinary skill in the art would not envision one in view of the other. Therefore, they are separate and patentably distinct species

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 27, 2000